

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
NORTHEASTERN DIVISION**

**CATHIE WELLER, individually,
and as the personal representative
of the Estate of JAMES
HETHERINGTON,**

Plaintiff,

vs.

**UNITED STATES OF
AMERICA,**

Defendant.

Civil Action No. CV-07-S-01706-NE

MEMORANDUM OPINION

This action is based upon the Federal Tort Claims Act. *See* 28 U.S.C. § 1346(b)(1) and §§ 2671-2680. The plaintiff is Cathie Weller, who sues both individually and as personal representative of the estate of her deceased father, James Hetherington. Plaintiff's claims for alleged medical negligence ("malpractice") and wrongful death arise out of the treatment provided to her father by the healthcare providers employed at the Louis Stokes Veterans Administration Medical Center in Cleveland, Ohio ("Cleveland VAMC") during the months of July, August, and September of 2003.¹ The case presently is before the court on cross motions. The United States of America ("defendant" or "the government") moves for summary

¹ *See* doc. no.1 (Complaint); doc. no. 23 (Amended Complaint).

judgment on all of plaintiff's claims,² arguing that plaintiff's administrative claim was not received by the appropriate federal agency within two years of her decedent's death and, as a result, plaintiff's claims are barred by the applicable statutes of limitation. *See* 28 U.S.C. § 2401(b), § 2675(a), and 28 C.F.R. § 543.30 *et seq.*³ The government also seeks to exclude the testimony of plaintiff's medical witnesses on the issues of causation and the applicable standard of care, arguing that their opinions are not reliable.⁴ *See* Fed. R. Evid. 702; *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

In like manner, plaintiff moves to exclude the opinions and testimony of the government's medical expert, but on the grounds that his report was untimely.⁵ Plaintiff also moves for partial summary judgment on her medical negligence claim, arguing that, because defendant failed to identify in a timely manner an expert witness to address the issue of the applicable standard of care, plaintiff's evidence concerning the negligence of Cleveland VAMC's health care providers was uncontroverted.⁶ Upon consideration, and for the reasons discussed below, the government's motion to exclude the testimony and opinions of plaintiff's experts will

² Doc. no. 49.

³ *See* doc. no. 50, at 11-18.

⁴ *Id.* at 18-24.

⁵ *See* doc. no. 53, at 6-7.

⁶ *Id.* at 7-11.

be granted. In the absence of evidence to support plaintiff's theory of causation, the government's motion for summary judgment also must be, and accordingly will be, granted. Plaintiff's motions to exclude the testimony of the government's expert, and for partial summary judgment on the issue of negligence, will be denied as moot.

I. STANDARDS OF REVIEW

Federal Rule of Civil Procedure 56 provides that summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).⁷ In other words, summary judgment is proper "after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "In making this determination, the court must review all evidence and make all reasonable inferences in favor of the party opposing summary judgment." *Chapman v. AI Transport*, 229 F.3d 1012, 1023 (11th Cir. 2000) (*en banc*) (quoting *Haves v.*

⁷ Rule 56 was recently amended in conjunction with a general overhaul of the Federal Rules of Civil Procedure. The Advisory Committee was careful to note, however, that the changes "are intended to be *stylistic only*." Adv. Comm. Notes to Fed. R. Civ. P. 56 (2007 Amends.) (emphasis supplied). Consequently, cases interpreting the previous version of Rule 56 are equally applicable to the revised version.

City of Miami, 52 F.3d 918, 921 (11th Cir. 1995)). Inferences in favor of the non-moving party are not unqualified, however. “[A]n inference is not reasonable if it is only a guess or a possibility, for such an inference is not based on the evidence, but is pure conjecture and speculation.” *Daniels v. Twin Oaks Nursing Home*, 692 F.2d 1321, 1324 (11th Cir. 1983). Moreover,

[t]he mere existence of some factual dispute will not defeat summary judgment unless that factual dispute is *material* to an issue affecting the outcome of the case. The relevant rules of substantive law dictate the materiality of a disputed fact. A genuine issue of material fact does not exist unless there is sufficient evidence favoring the nonmoving party for a reasonable jury to return a verdict in its favor.

Chapman, 229 F.3d at 1023 (quoting *Haves*, 52 F.3d at 921) (emphasis supplied). See also *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52 (1986) (asking “whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law”).

When presented with cross motions for summary judgment, “[t]he court must rule on each party’s motion on an individual and separate basis, determining, for each side, whether a judgment may be entered in accordance with the Rule 56 standard.” 10A Wright, Miller & Kane, *Federal Practice and Procedure: Civil 3d* § 2720, at 335-36 (1998) (footnote omitted); see also, e.g., *Arnold v. United States Postal Service*, 649 F. Supp. 676, 678 (D. D.C. 1986). Further, the court is required to

“relate all material facts in genuine dispute in the light most favorable to the party resisting summary judgment.” *Serrano-Cruz v. DFI Puerto Rico, Inc.*, 109 F.3d 23, 24 (1st Cir. 1997) (citing *Sanchez v. Alvarado*, 101 F.3d 223, 225 n.1 (1st Cir. 1996)).

II. SUMMARY OF FACTS AND PROCEDURAL HISTORY

James Hetherington was a 59-year-old Caucasian male with a history of multiple medical problems, including focal mesangial proliferative glomerulonephritis⁸ with ANCA positive vasculitis,⁹ coronary artery disease with myocardial infarction,¹⁰ Sjögren’s Syndrome,¹¹ hypertension,¹² dyslipidemia,¹³

⁸ *Nephritis* is “inflammation of the kidney.” *Dorland’s Illustrated Medical Dictionary* 1229 (Douglas M. Anderson *et al.* ed., 30th ed. 2003) (“**Dorland’s**”). *Glomerulo[-]nephritis* is defined as “nephritis accompanied by inflammation of the capillary loops in the renal glomeruli. It occurs in acute, subacute, and chronic forms and may be secondary to hemolytic streptococcal infection. Evidence also supports possible immune or autoimmune mechanisms.” *Id.* at 779. *Mesangial proliferative glomerulonephritis* is “a kidney disorder characterized by swelling and blood in the urine (dark urine). It is caused by inflammation of an internal kidney structure (glomerulus), and specifically an increase in number of certain glomerular cells (mesangial cells), accompanied by antibody deposits in the mesangium layer of the glomerular capillary.” Dictionary.com, A.D.A.M. Medical Encyclopedia, <http://www.drugs.com/enc/mesangial-proliferative-glomerulonephritis.html> (last visited Nov. 6, 2009).

⁹ *Vasculitis* is “the inflammation of a blood or lymph vessel.” *Dorland’s*, at 2009.

¹⁰ *A myocardial infarction*, commonly called a heart attack or MI, is a “gross necrosis of the myocardium as a result of interruption of the blood supply to the area; it is almost always caused by atherosclerosis of the coronary arteries, upon which coronary thrombosis is usually superimposed.” *Id.* at 928.

¹¹ *Sjögren’s syndrome* is “a symptom complex of unknown etiology, usually occurring in middle-aged or older *women*, marked by the triad of keratoconjunctivitis sicca with or without lacrimal gland enlargement, xerostomia with or without salivary gland enlargement, and the presence of a connective tissue disease, usually rheumatoid arthritis but sometimes systemic lupus erythematosus, scleroderma, or polymyositis. An abnormal immune response has been indicated.” *Id.* at 1832 (emphasis supplied).

¹² *Hypertension* is “high arterial blood pressure; various criteria for its threshold have been suggested, ranging from 140 mm Hg systolic and 90 mm Hg diastolic to as high as 200 mm Hg

eczema,¹⁴ and shingles.¹⁵

Mr. Hetherington first presented to the Cleveland VAMC for treatment in March of 2003, complaining of fatigue, cough, anemia, and renal failure.¹⁶ During that admission, he was found to have focal mesangial proliferative glomerulonephritis with ANCA positive vasculitis and Sjogren's Syndrome: conditions that were treated with medications, including cytoxan and prednisone.¹⁷

In May of 2003, Mr. Hetherington had an episode of shingles after beginning

systolic and 110 mm Hg diastolic. Hypertension may have no known cause (essential or idiopathic h.) or be associated with other primary diseases (secondary h.)" *Dorland's*, at 889.

¹³ *Dyslipidemia* is "abnormality in, or abnormal amounts of, lipids and lipoproteins in the blood." *Id.* at 575.

¹⁴ *Eczema* is "a pruritic papulovesicular dermatitis occurring as a reaction to many endogenous and exogenous agents, characterized in the acute stage by erythema, edema associated with a serous exudate between the cells of the epidermis (spongiosis) and an inflammatory infiltrate in the dermis, oozing and vesiculation, and crusting and scaling; and in the more chronic stages by lichenification or thickening or both, signs of excoriations, and hyperpigmentation or hypopigmentation or both." *Id.* at 588.

¹⁵ See doc. no. 51 (Evidentiary Materials in Support of Defendant's Motion for Summary Judgment), Ex. 2 (Deposition of Cathie Weller), Ex. 6 (Cleveland VAMC Medical Records dated Sept. 15, 2003). *Herpes zoster*, or "shingles," is "an acute infectious, usually self-limited, disease believed to represent activation of a latent human herpes virus 3 in those who have been rendered partially immune after a previous attack of chicken pox. It involves severe neuralgic pain along the distribution of the affected nerve and crops of clustered vesicles over the area of the corresponding dermatome, and is usually unilateral and confined to a single or adjacent dermatomes. Postherpetic neuralgia may be a complication. In immunocompromised patients it may disseminate and be fatal." *Dorland's*, at 845.

¹⁶ See doc. no. 51 (Evidentiary Materials in Support of Defendant's Motion for Summary Judgment), Ex. 2 (Deposition of Cathie Weller), Ex. 6 (Cleveland VAMC Medical Records dated Sept. 15, 2003).

¹⁷ See *id.*

a medication called plavix.¹⁸

In early July of 2003, Mr. Hetherington was admitted to the Cleveland VAMC for acute coronary syndrome with a myocardial infarction (“heart attack”), at which time intercoronary stents were implanted in blood vessels of his heart.¹⁹ In order to control Mr. Hetherington’s heart condition, doctors at the Cleveland VAMC prescribed multiple medications, including plavix, ticlid,²⁰ and a beta blocker called metoprolol.²¹

¹⁸ See *id.* Plavix, generically known as “clopidogrel,” is “an inhibitor of platelet aggregation. A variety of drugs that inhibit platelet function have been shown to decrease morbid events in people with established cardiovascular atherosclerotic disease as evidenced by stroke or transient ischemic attacks, myocardial infarction, unstable angina or the need for vascular bypass or angioplasty. This indicates that platelets participate in the initiation and/or evolution of these events and that inhibiting them can reduce the event rate.” Thompson Healthcare, *Physician’s Desk Reference, Prescription Drugs*, Database updated February 2009, at 7308-1610 (“Physician’s Desk Reference”).

¹⁹ See doc. no. 51, Ex. 5 (Deposition of Dr. Moshell), at 22. See also *supra* note 10.

²⁰ Ticlid, generically known as “ticlopidine hydrochloride,” is “a platelet aggregation inhibitor.” Thompson Healthcare, *Physician’s Desk Reference, Prescription Drugs*, Database updated August 2008, at 6920-2800. “When taken orally, ticlopidine hydrochloride causes a time- and dose-dependent inhibition of both platelet aggregation and release of platelet granule constituents, as well as a prolongation of bleeding time.” *Id.*

²¹ See doc. no. 51, Ex. 2 (Deposition of Cathie Weller), Ex. 6 (Cleveland VAMC Medical Records dated Sept. 15, 2003); doc. no. 56 (Evidentiary Materials in Support of Plaintiff’s Response to Defendant’s Motion for Summary Judgment), Ex. 9 (Deposition of Dr. Gelles), at 37. *Metoprolol* is

a betal-selective (cardioselective) adrenergic receptor blocking agent. This preferential effect is not absolute, however, and at higher plasma concentrations, metoprolol also inhibits beta2-adrenoreceptors, chiefly located in the bronchial and vascular musculature. Metoprolol has no intrinsic sympathomimetic activity, and membrane-stabilizing activity is detectable only at plasma concentrations much greater than required for beta-blockade. Animal and human experiments indicate that metoprolol slows the sinus rate and decreases AV nodal conduction.

On July 23, 2003, Mr. Hetherington complained of a rash.²² Because the rash improved when plavix was discontinued, the rash was thought to be the result of that medication; Ticlid also was discontinued because the rash worsened with its administration.²³

One month later, on August 24, 2003, Mr. Hetherington again was admitted to the Cleveland VAMC with multiple complaints, including the presence of a worsening rash on his chest, arms, legs, and trunk, as well as diarrhea, nausea, and vomiting.²⁴ His physicians formed the impression that the rash was due to a reaction to medication, identifying the three most likely candidates for the offending drug as “plavix *versus* ticlid *versus* metoprolol.”²⁵ Upon admission, all outpatient

Clinical pharmacology studies have confirmed the beta-blocking activity of metoprolol in man, as shown by (1) *reduction in heart rate and cardiac output at rest and upon exercise*, (2) *reduction of systolic blood pressure upon exercise*, (3) *inhibition of isoproterenol-induced tachycardia*, and (4) *reduction of reflex orthostatic tachycardia*.

Physician's Desk Reference, at 0400-4000 (emphasis supplied).

²² See doc. no. 51, Ex. 2 (Deposition of Cathie Weller), Ex. 6 (Cleveland VAMC Medical Records dated Sept. 15, 2003).

²³ See *id.* The withdrawal of these two drugs, plavix and ticlid, apparently was a clinical procedure that the Eleventh Circuit described as a “dechallenge test” in *Rider v. Sandoz Pharmaceuticals Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002) (“A test is a ‘dechallenge’ test when a drug that is suspected of causing a certain reaction is withheld to see if the reaction dissipates.”).

²⁴ See doc. no. 51, Ex. 2 (Deposition of Cathy Weller), Ex. 6 (Cleveland VAMC Medical Records dated Sept. 15, 2003).

²⁵ See doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), at 72; Ex. 9 (Deposition of Dr. Gelles), Ex. 1 (Medical Records dated Sept. 16, 2003).

medications were discontinued except for prednisone, cytoxan, and clonidine,²⁶ and Mr. Hetherington was given lansoprazole, a proton pump inhibitor, from August 24th through the 29th.²⁷ He was also treated for an underlying infection with levofloxacin, an antibiotic, on August 30th and 31st, and vancomycin, another antibiotic, from August 28th through the 31st.²⁸ On August 29th, the dermatology service noted in Mr. Hetherington's medical records that a laboratory evaluation of a skin biopsy performed four days earlier was consistent with a drug-related rash.²⁹

On September 1st, Dr. Ellen Gelles, Mr. Hetherington's primary treating physician at the Cleveland VAMC, recorded that he was feeling much better "with improvement in weakness and resolution of diarrhea."³⁰ She also recorded that she had discussed the possibility of restarting some of Mr. Hetherington's cardiac medications, although she "planned to hold off for today, as this is the first day he is improving."³¹ During her deposition in connection with this case, Dr. Gelles testified

²⁶ See doc. no. 54 (Evidentiary Materials in Support of Plaintiff's Motion to Exclude Dr. Alvin [sic] Goldstein, M.D. and Motion for Summary Judgment), Ex. A. (Report of Dr. Elewski), at 1.

²⁷ See *id.*

²⁸ See *id.*

²⁹ See doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), at 72, and Ex. 1 (Cleveland VAMC Medical Records dated Aug. 29, 2003).

³⁰ Doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), Ex. 1 (Cleveland VAMC Medical Records dated Sept. 1, 2003).

³¹ *Id.*

that, throughout the course of Mr. Hetherington's treatment, he was "intermittently very tachycardic while in the hospital [*i.e.*, his heart beat was excessively rapid³²], which is dangerous for somebody who has just had a heart attack."³³

The following day, September 2nd, Dr. Gelles resumed administration of metoprolol, the beta blocker that had been prescribed following Mr. Hetherington's heart attack in early July.³⁴ She recorded in his medical chart that the "[b]ig intervention was to re-start beta blocker, *as this was unlikely the culprit for hypersensitivity syndrome*, and he is less than 2 months out [from myocardial infarction]."³⁵ In her deposition, Dr. Gelles elaborated on her written explanation for the decision to resume administration of metoprolol by saying that "it is the standard of care to give beta blockers after a myocardial infarction to prevent death."³⁶ Dr. Gelles testified that metoprolol was "an essential medication and unlikely to be the cause of his rash . . . because beta blockers are not common causes of drug rashes."³⁷

³² *Tachycardia* is "excessive rapidity in the action of the heart; the term is usually applied to a heart rate above 100 beats per minute in an adult and is often qualified by the locus of origin as well as by whether it is paroxysmal or nonparoxysmal." *Dorland's*, at 1850.

³³ Doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), at 44.

³⁴ *Id.* at 48-49.

³⁵ *Id.*, Ex. 1 (Cleveland VAMC Medical Records dated Sept. 2, 2003) (emphasis supplied). As noted in *Rider v. Sandoz Pharmaceuticals*, see *supra* note 23 (discussing a "dechallenge test"), the resumption of a drug that was discontinued in order to see if a reaction dissipates constitutes a "rechallenge test." See 295 F.3d at 1199 ("The drug may then be reintroduced in a 'rechallenge' to see if the reaction reoccurs.").

³⁶ See doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), at 37; 41-42.

³⁷ *Id.*

On the same day, however, Dr. Gelles also noted in medical records that she had engaged in an “extensive discussion with [Mr. Hetherington and his] wife regarding uncertainties surrounding diagnosis (e.g. which drug caused this, expected course from here, etc).”³⁸

On September 4th, two days after resumption of metoprolol, Dr. Gelles documented that Mr. Hetherington’s clinical status had not changed significantly, and that she had another long discussion with him, his wife, and their daughter (plaintiff herein) about Mr. Hetherington’s medical status.³⁹

Medical records for the following day, September 5th, reflected that Mr. Hetherington’s symptoms and appearance had improved, and that his dosage of metoprolol was increased.⁴⁰ Mr. Hetherington also reported that he continued to feel better, despite significant sloughing of the skin on his legs.⁴¹

Two days later, on September 7th, Mr. Hetherington’s medical records reflected that, even though he complained of increased urinary frequency, sleeplessness, and tremor, he denied feeling pain.⁴² The examining physician,

³⁸ *Id.*

³⁹ *Id.*, Ex. 1 (Cleveland VAMC Medical Records dated Sept. 4, 2003).

⁴⁰ *Id.* (Cleveland VAMC Medical Records dated Sept. 5, 2003).

⁴¹ *Id.* (Cleveland VAMC Medical Records dated Sept. 6, 2003).

⁴² *See* doc. no. 51, Ex. 5 (Deposition of Dr. Moshell), Ex. 4 (Cleveland VAMC Medical Records dated Sept. 7, 2003).

medical student Benjamin Lind, again documented that Mr. Hetherington was “[o]verall feeling better.”⁴³ Dr. Gelles concurred, noting that “[o]verall, condition [was] improving.”⁴⁴

On September 8th, Mr. Hetherington began experiencing diarrhea, but the rheumatologist who examined him noted that his rash was resolving.⁴⁵ The medical records indicated that Mr. Hetherington was “upset over [his] current state,” and that he (Mr. Hetherington) believed “it was due to metoprolol, which he now refuses to take.”⁴⁶ Later on the same day, Mr. Hetherington “was adamant that [his] urinary frequency and agitation [were] due to metoprolol, and he insisted on being switched from metoprolol to clonidine for [blood pressure] control.”⁴⁷ Dr. Gelles testified that she documented Mr. Hetherington’s refusal of metoprolol because she “felt that metoprolol was the preferred medication to be given in the setting of a patient who had a previous recent myocardial infarction.”⁴⁸ Nevertheless, due to Mr. Hetherington’s refusal, the administration of metoprolol was discontinued against doctors’ recommendations.

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ See doc. no. 51, Ex. 2 (Deposition of Cathie Weller), Ex. 7 (Cleveland VAMC Medical Records dated Sept. 8, 2003).

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ Doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), at 55.

On September 9th, Mr. Hetherinton continued to complain of urinary frequency, but his records reflected a slight improvement in his skin condition.⁴⁹

On September 11th, Mr. Hetherington's medical records reflected his desire to have his case reviewed for a second opinion.⁵⁰ His medical chart documents that he reiterated this desire the following day.⁵¹ On both occasions, Dr. Gelles spoke with Mr. Hetherington and his wife about his options for obtaining a second opinion.⁵² Dr. Gelles noted that "patient's wife (and to a lesser extent, Mr. Hetherington) are expressing a lot of frustration that 'he is not better.'"⁵³ Later in the same notation, Dr. Gelles wrote that she "welcomed them to pursue transfer to the CCF [*i.e.*, Cleveland Clinic Foundation] if they would like."⁵⁴

The records for September 12th show that Mr. Hetherington's skin remained "diffusely erythematous⁵⁵ and desquamating,"⁵⁶ and that he was "tachycardic and

⁴⁹ See doc. no. 51, Ex. 1 (Deposition of Cathie Weller), Ex. 7 (Cleveland VAMC Medical Records dated Sept. 9, 2003).

⁵⁰ *Id.* (Cleveland VAMC Medical Records dated Sept. 11, 2003).

⁵¹ *Id.* (Cleveland VAMC Medical Records dated Sept. 12, 2003).

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Erythema* is "redness of the skin produced by congestion of the capillaries." *Dorland's*, at 638.

⁵⁶ *Disquamation* is defined as exfoliation. *Id.* at 501.

slightly hypertensive and afebrile.”⁵⁷ The following day, the medical records showed that, even though Mr. Hetherington was tachycardic, he continued to refuse the beta blocker metoprolol to control his heart condition, and that he was “currently on clonidine only for [blood pressure] control.”⁵⁸

According to notations made by Dr. Gelles in Mr. Hetherington’s medical records two days later, on September 14th, his skin condition changed.⁵⁹ Dr. Gelles found diffuse bullae,⁶⁰ which she described as big blisters on Mr. Hetherington’s skin.⁶¹ Dr. Gelles wrote: “will consider having dermatology re-examine the skin, though I suspect that the new bullae are all part of normal resolution of this erythrodermic drug reaction.”⁶² Dr. Gelles also noted that, “if [patient is] agreeable, re-initiation of beta blocker would be helpful in this man who so recently had a

⁵⁷ See doc. no. 51, Ex. 1 (Deposition of Cathie Weller), Ex. 7 (Cleveland VAMC Medical Records dated Sept. 12, 2003). *Tachycardia* was defined in note 32, *supra*, as “excessive rapidity in the action of the heart; the term is usually applied to a heart rate above 100 beats per minute in an adult and is often qualified by the locus of origin as well as by whether it is paroxysmal or nonparoxysmal.” *Hypertension* was defined in note 12, *supra*, as “high arterial blood pressure; various criteria for its threshold have been suggested, ranging from 140 mm Hg systolic and 90 mm Hg diastolic to as high as 200 mm Hg systolic and 110 mm Hg diastolic. Hypertension may have no known cause (essential or idiopathic h.) or be associated with other primary diseases (secondary h.)” *Afebrile* means “without fever.” *Dorland’s*, at 36.

⁵⁸ See doc. no. 51, Ex. 1 (Deposition of Cathie Weller), Ex. 7 (Cleveland VAMC Medical Records dated Sept. 13, 2003).

⁵⁹ See doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), at 60-61.

⁶⁰A *bullae* is “a large elevation of the skin, containing serous or seropurulent fluid.” *Dorland’s*, at 259. *Diffuse* means “not definitely localized; widely distributed.” *Id.* at 516.

⁶¹ See doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), at 60-61.

⁶² *Id.*

coronary ischemic event.”⁶³ The records show that beta blocker metoprolol was in fact re-initiated that same day, September 14th, and it was administered to Mr. Hetherington along with fourteen other medications.⁶⁴

On September 15th, Dr. Gelles observed that the patient “appears overall worse today, with continued tachycardia and rupture of the bullous lesions noted on skin yesterday.”⁶⁵ Dr. Gelles discussed the case with the attending dermatology physician, Dr. Kevin Cooper, and wrote that Dr. Cooper’s “clinical impression is that [Mr. Hetherington] has Stevens Johnson/TEN.”⁶⁶ Stevens-Johnson syndrome is

a sometimes fatal form of erythema multi-forme having a flulike prodrome and systemic as well as more severe mucocutaneous lesions. Oronasal and anogenital mucous membranes may develop a characteristic gray or white pseudomembrane, and hemorrhagic crusts often occur on the lips. Ocular lesions may include injected conjunctivitis, iritis, uveitis, corneal vesicles, erosions, and perforation, which may result in corneal opacities and blindness. Pulmonary, gastrointestinal, cardiac, and renal involvement also occur.⁶⁷

“TEN,” the acronym for toxic epidermal necrolysis, is

an exfoliative skin disease seen primarily in adults as a severe cutaneous reaction to various factors, usually drugs but sometimes infections (viral, bacterial, or fungal), neoplastic disease, graft-versus-host reaction, or

⁶³ Doc. no. 51, Ex. 1 (Deposition of Cathie Weller), Ex. 7 (Cleveland VAMC Medical Records dated Sept. 14, 2003).

⁶⁴ *Id.*

⁶⁵ *Id.* (Cleveland VAMC Medical Records dated Sept. 15, 2003).

⁶⁶ *Id.*

⁶⁷ *Dorland's*, at 1833.

chemical exposure. It is characterized by full-thickness epidermal necrosis, resulting in subepidermal separation, bulla formation, and dermal inflammatory changes; there is widespread loss of skin, leaving raw areas where the skin surface looks scalded.⁶⁸

Dr. Gelles noted that, “[i]f biopsies taken today indeed reveal TEN, and clinical status does not improve, [Mr. Hetherington] may need transfer to Metro Burn Unit.”⁶⁹

In the early afternoon of the same day, September 15th, Mr. Hetherington was transferred to the Cleveland VAMC intensive care unit (“ICU”).⁷⁰ At that time, his medical chart recorded that his skin rash had become “significantly worse, with ruptured bullae and extensive weeping.”⁷¹ Shortly after the transfer to ICU, the dermatologist reported that Mr. Hetherington’s biopsy was consistent with Stevens Johnson Syndrome, with suspected progression to toxic epidermal necrolysis, or “TEN.”⁷²

By the next morning, September 16, 2003, Mr. Hetherington’s “skin lesions were clearly progressing,” and his respiratory status was becoming “more compromised.”⁷³ At approximately 2:15 that afternoon, he was transferred from

⁶⁸ *Id.* at 1224.

⁶⁹ Doc. no. 51, Ex. 1 (Deposition of Cathie Weller), Ex. 7 (Cleveland VAMC Medical Records dated Sept. 15, 2003).

⁷⁰ *See id.*

⁷¹ *Id.*

⁷² *See id.*

⁷³ Doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), Ex. 1 (Medical Records dated Sept. 16, 2009).

Cleveland VAMC's intensive care unit to the burn unit at a non-governmental hospital, MetroHealth Medical Center ("MetroHealth").⁷⁴ Upon his arrival, "he was felt to be in florid septic shock."⁷⁵ The admission records indicated that Mr. Hetherington had "intense reddening of the skin on all surfaces, no current bullae, but areas where bullae likely were now popped, leaking copious amount of serous fluids from all extremities and trunk."⁷⁶ At 3:00 p.m., Mr. Hetherington was still in the admission area having his wounds treated when he went into asystolic arrest.⁷⁷ He could not be revived, and was pronounced dead shortly thereafter.⁷⁸

Dr. Charles J. Yarrow, who had briefly evaluated and treated Mr. Hetherington at the MetroHealth Medical Center burn unit, explained to plaintiff that her father had developed toxic epidermal necrolysis while he was being treated at the VA Hospital, and that the condition had caused his death.⁷⁹ The death certificate signed by the Cuyahoga County, Ohio Medical Examiner on September 30, 2003, and issued on October 1, 2003, indicated that Mr. Hetherington's cause of death was "Toxic epidermal necrolysis ('TEN') due to multiple prescribed medications (Plavix, Ticlid,

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *See id.* Asystole is the "absence of a heartbeat." *Dorland's*, at 170.

⁷⁸ *See id.*

⁷⁹ Doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), Ex. 1 (Medical Records dated Sept. 16, 2009).

and/or Metoprolol).”⁸⁰

Cathie Weller mailed an administrative claim to the Department of Veterans Affairs on Standard Form 95 by means of certified, priority mail on September 9, 2005, seven days prior to the second anniversary of her father’s death.⁸¹ For some reason unknown to the U.S. Postal Service, the claim form was not delivered within the guaranteed two-to-three day period. In fact, the postal service did not attempt to deliver the parcel until the peculiar time and date of 3:46 a.m. on Sunday, September 18, 2005.⁸² The parcel was finally received by the VA Office of Regional Counsel in Washington, D.C. on September 20, 2005.⁸³ The VA Office of Regional Counsel in Cleveland, Ohio received the administrative claim on September 28, 2009.⁸⁴ Because the delivery of plaintiff’s parcel occurred well outside of the U.S. Postal Service’s normal procedures, the Postmaster provided plaintiff a statement accepting responsibility for the delay, and requesting the receiving party, the Department of Veterans Affairs, to consider the parcel as having been delivered in a timely manner.⁸⁵

The Department of Veterans Affairs formally denied plaintiff’s claim on

⁸⁰ See doc. no. 51, Ex. 1 (Certificate of Death).

⁸¹ See doc. no. 51, Ex. 1 (Certified Mail Receipt dated 09/09/2005).

⁸² See doc. no. 51, Ex. 1 (Track & Confirm Search Results).

⁸³ See doc. no. 51, Ex. 1 (Statement of Postmaster, Cynthia Obrien).

⁸⁴ See *id.*

⁸⁵ See *id.*

November 30, 2006.⁸⁶ Plaintiff filed her request for reconsideration on December 21, 2006, and received a notice of final denial on March 29, 2007.⁸⁷ Plaintiff filed her complaint in this court less than six months later, on September 19, 2007.⁸⁸

On March 4, 2008, the court entered a scheduling order that established deadlines by which the parties were required to designate their expert witnesses pursuant to Federal Rule of Civil Procedure 26(a)(2).⁸⁹ That order incorporated the report of the parties' planning meeting, which provided for disclosure of plaintiff's retained experts by July 1, 2008, and defendant's retained experts by September 2, 2008.⁹⁰ On June 10, 2008, the court extended by sixty days the deadlines contained in the original scheduling order.⁹¹

Plaintiff designated her expert witnesses on August 29, 2008, in accordance with the scheduling order. Specifically, plaintiff designated Dr. Edward Taylor, an internist, to offer opinions regarding alleged breaches of the applicable standard of care by agents and employees of the United States.⁹² At the same time, plaintiff

⁸⁶ See doc. no. 51, Ex. 1 (Letter of Denial).

⁸⁷ See doc. no. 51, Ex. 1 (Request for Reconsideration) and (Final Notice of Denial).

⁸⁸ Doc. no. 1.

⁸⁹ Doc. no. 26.

⁹⁰ See *id.*

⁹¹ See doc. no. 32 (Motion for Extension of Time); order entered on June 10, 2008 granting motion for extension of time.

⁹² See doc. no. 54 (Evidentiary Materials in Support of Plaintiff's Motion to Exclude Dr. Alvin [sic] Goldstein, M.D. and Motion for Summary Judgment), Ex. A. (Report of Dr. Edward

designated a dermatologist, Dr. Alan Moshell, to provide opinions primarily regarding causation issues, but also concerning defendant's compliance with the applicable standard of care.⁹³

On the date for disclosing its expert witnesses, the government designated a single medical witness, Dr. Boni Elewski, a dermatologist. Dr. Elewski's report primarily addressed issues of causation.⁹⁴ The government filed a second Rule 26 disclosure on February 2, 2009, which identified a new medical witness, Dr. Allan Goldstein.⁹⁵ Dr. Goldstein's report addressed issues relating to compliance with the standard of care.⁹⁶

III. DISCUSSION

A. The Statute of Limitations

The United States, as sovereign, "is immune from suit save as it consents to be sued . . . and the terms of its consent to be sued in any court define the court's jurisdiction to entertain the suit." *Lehman v. Nakshian*, 453 U.S. 156, 160 (1980) (quoting *United States v. Testan*, 424 U.S. 392, 399 (1941)) (internal quotation marks omitted). The Federal Tort Claims Act ("FTCA") provides a limited waiver of the

Taylor).

⁹³ See doc. no. 54., Ex. B (Report of Dr. Alan Moshell).

⁹⁴ See doc. no. 54, Ex. E (Report of Dr. Boni Elewski).

⁹⁵ See doc. no. 54, Ex. F (Defendant's Amended Initial Disclosures).

⁹⁶ See doc. no. 54, Ex. G (Report of Dr. Allan Goldstein).

United States' sovereign immunity from tort claims for

money damages . . . for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred.

28 U.S.C. § 1346(b). The applicable statute of limitation reads as follows:

A tort claim against the United States shall be forever barred unless it is presented in writing to the appropriate Federal Agency *within two years after such claim accrues* or unless action is begun within six months after the date of mailing, by certified or registered mail, of notice of final denial of the claim by the agency to which it is presented.

28 U.S.C. § 2401(b) (emphasis supplied); *see also id.* § 2675(a) and 28 C.F.R. § 543.30 *et seq.*

Claims for medical negligence under the FTCA are deemed to accrue “when a claimant discovers, or in the exercise of reasonable diligence should have discovered, the acts constituting the alleged malpractice.” *Burgess v. United States*, 744 F.2d 771, 773 (11th Cir. 1984) (citations omitted); *see also Price v. United States*, 775 F.2d 1491, 1494 (11th Cir. 1985) (holding that “a medical malpractice claim under the FTCA accrues when the plaintiff is, or in the exercise of reasonable diligence should be, aware of both her injury and its connection with some act of the defendant”). This principle has been extended to wrongful death claims under the

FTCA, and such claims are deemed to accrue “when the plaintiff knows, or exercising reasonable diligence should know, both of the decedent’s death and its causal connection with the government.” *Diaz v. United States*, 165 F.3d 1337, 1340 (11th Cir. 1999).

The government argues that plaintiff’s claims are barred by the two-year statute of limitations quoted above, because her claims accrued on September 16, 2003, the date of Mr. Hetherington’s death, and the federal agency did not receive plaintiff’s administrative claims until September 20, 2005, four days past the two year anniversary of his death.⁹⁷

Plaintiff argues, however, that the statute should run from October 1, 2003, the date of filing her father’s death certificate (stating that Mr. Hetherington’s cause of death was “Toxic epidermal necrolysis (‘TEN’) due to multiple prescribed medications (Plavix, Ticlid, and/or Metoprolol)”).⁹⁸ Plaintiff explains that she was unaware of the connection between her father’s death and the medications administered by the VA Medical Center “until after the death certificate was filed on

⁹⁷ See doc. no. 50, at 11-18.

⁹⁸ See doc. no. 56, at 9. In response to defendant’s first motion for summary judgment regarding the statute of limitations issue, plaintiff argued that the statute of limitations should run from the date on which the death certificate was signed, September 30, 2009. See doc. no. 8 (Plaintiff’s Brief in Opposition to Defendant’s Motion for Summary Judgment), at 4. The distinction between the two different dates that plaintiff has identified as the date of accrual, September 30th and October 1st, is immaterial for the purpose of evaluating the defendant’s argument on the issue of the applicable statute of limitations.

October 1, 2003.”⁹⁹

This issue was first raised in a motion for summary judgment filed by the government in lieu of an answer to plaintiff’s complaint.¹⁰⁰ Judge Clemon, to whom this action was assigned prior to his retirement, denied that motion on January 8, 2008, finding that “nothing in the evidence establishes that, on the date of her father’s death, Ms. Weller became aware that the VA may have caused [his] death.”¹⁰¹ Judge Clemon found the existence of a genuine issue of material fact with respect to the precise date upon which plaintiff discovered or, in the exercise of reasonable diligence, should have discovered the acts constituting the alleged medical malpractice.¹⁰²

In support of its present motion for summary judgment on this issue, the government relies upon the same arguments previously rejected by Judge Clemon. For example, the government emphasizes that Mr. Hetherington’s medical records at the time of his death showed that a drug reaction causing TEN led to his death.¹⁰³ The only new evidence offered by the government is the fact that, during plaintiff’s deposition, she “admits that she and other family members, on September 16, 2003,

⁹⁹ Doc. no. 56, at 9.

¹⁰⁰ *See* doc. no. 3 (“Defendant’s First Motion for Summary Judgment,” filed Oct. 30, 2007).

¹⁰¹ Doc. no. 11, at 4.

¹⁰² *See id.*

¹⁰³ *See* doc. no. 50, at 16.

were informed by Dr. Yarrow at the Metro Hospital that Mr. Hetherington had TEN (toxic epidermal necrolysis) upon his arrival from the VA hospital and that this was the cause of his death.”¹⁰⁴ The government then argues that, based upon the information conveyed by Dr. Yarrow, and the information available in Mr. Hetherington’s medical records on the date of his death, plaintiff “knew or should have known to look to the VA doctors and other VA health care providers for any responsibility in Mr. Hetherington’s cause of death.”¹⁰⁵ However, this court is not convinced that this evidence goes any further toward establishing that plaintiff either had discovered, or should have discovered, the acts constituting the alleged malpractice on the date of her father’s death. To the contrary, plaintiff testified that, when she spoke to Dr. Yarrow just after the death of her father, she did not know what TEN was, and did not know that it was connected to drug reactions.¹⁰⁶

The government also relies upon plaintiff’s admission that, as early as September 12, 2003, she and other family members were “not happy” with the treatment given to Mr. Hetherington by the VA doctors and other health care providers.¹⁰⁷ “Mere dissatisfaction with the results of medical treatment, however, is

¹⁰⁴ *Id.* at 17.

¹⁰⁵ *See id.* at 16-17.

¹⁰⁶ *See* doc. no. 56, Ex. 7 (Deposition of Cathie Weller), at 25-26.

¹⁰⁷ *See* doc. no. 50, at 17.

not to be equated with knowledge of negligence.” *Waits v. United States*, 611 F.2d 550, 553 (5th Cir. 1980). In *Waits*, the former Fifth Circuit held that a plaintiff’s FTCA claim was not time-barred after considering arguments similar to those asserted by the government in this case. *Id.*¹⁰⁸ The patient in *Waits* was treated for a broken leg at a VA hospital and developed an infection. *Id.* at 551. After becoming dissatisfied with the treatment he was receiving at the VA hospital, the patient was transferred to a non-government hospital on January 5, 1973. *Id.* There, it was determined that the antibiotic administered at the VA hospital was not an effective drug for treating the agent causing his infection. *Id.* Because of the delay in receiving an effective antibiotic, the infection had advanced to a stage that required amputation of the patient’s leg. *Id.* An administrative claim was filed on January 24, 1975. *Id.* at 552. After suit was filed, the government argued that the case was time-barred because, on or about January 5, 1973, the patient knew that he had an infection and was dissatisfied with the VA hospital’s medical treatment. *Id.* at 553. The court rejected this argument, holding that the issue was not whether the patient had an infection, or was not satisfied with the course of his treatment, but whether on the date of transfer, the patient had reason to think that his infection had not been treated

¹⁰⁸ In *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981) (*en banc*), the Eleventh Circuit adopted as binding precedent all decisions of the former Fifth Circuit handed down prior to the close of business on September 30, 1981.

properly. *Id.*

Here, plaintiff knew on September 16, 2003 that her father had developed toxic epidermal necrolysis while receiving treatment at the Cleveland VAMC, and that the condition had caused his death.¹⁰⁹ Even so, those facts do not alone establish that plaintiff connected the actions of VA employees with the cause of her father's death. Accordingly, a genuine issue of material fact remains as to the precise date upon which plaintiff discovered or, in the exercise of reasonable diligence, should have discovered the acts constituting the alleged medical malpractice. Because it is not clear that plaintiff's claim accrued on September 16, 2003, the government is not entitled to summary judgment based upon its statute of limitations argument.

In response to the government's first motion for summary judgment on the statute of limitations issue, plaintiff argued that, even if the court were to decide that her claim accrued on September 16, 2003, her delay in filing an administrative claim should be excused because she submitted her claim *via* certified, priority mail on September 9, 2005 — seven days before the applicable statutory deadline.¹¹⁰ Plaintiff argued that, because the U.S. Postal Service's inexplicable delay in delivering the parcel was beyond both her anticipation and ability to control, the four-day delay

¹⁰⁹ See doc. no. 56, Ex. 7 (Deposition of Cathie Weller), at 25.

¹¹⁰ See doc. no. 8, at 5-8.

should not bar her claim.¹¹¹ However, plaintiff does not reiterate that argument in her opposition to the government’s present motion for summary judgment. Although both parties acknowledge the Postal Service delay in their respective statements of fact,¹¹² neither the United States nor Ms. Weller address the issue in their present discussions of the statute of limitations issue. Because neither party cites any authority to support its position on the significance of the postal delay, the court will not address the possibility of equitable tolling.¹¹³ Stated differently, the court will not speculate on what arguments might be made, especially when they are not fully developed or bolstered with legal authority. *See, e.g., U.S. Steel Corp. v. Astrue*, 495 F.3d 1272, 1287 n.13 (11th Cir. 2007) (refusing to address a party’s “perfunctory and underdeveloped argument”) (citing *Flanigan’s Enterprises, Inc. v. Fulton County*, 242 F.3d 976, 987 n.16 (11th Cir. 2001) (holding that “fail[ure] to elaborate or provide any citation of authority in support [of an argument]” results in waiver)).¹¹⁴

¹¹¹ *See id.*

¹¹² *See* doc. no. 50, at 7-8; doc no. 56, at 3, ¶ 9.

¹¹³ *Compare Santos v. United States*, 559 F.3d 189, 197 (3rd Cir. 2009) (holding that the Federal Tort Claims Act’s statute of limitations is not jurisdictional and, therefore, principles of equitable tolling applicable to suits against private defendants also applies to suits against the United States to “rescue a claim otherwise barred as untimely . . . when a plaintiff has been prevented from filing in a timely manner due to sufficiently inequitable circumstances”) (citation and internal quotation marks omitted), *with Torjagbo v. United States*, 285 Fed. Appx. 615, 618 (11th Cir. 2008) (finding that the Federal Tort Claims Act’s statute of limitations is jurisdictional, but declining to determine whether equitable tolling applies).

¹¹⁴ *See also Lyes v. City of Riviera Beach, Fla.*, 126 F.3d 1380, 1388 (11th Cir. 1997) (explaining that “the onus is upon the parties to formulate arguments”); *Resolution Trust Corp. v.*

B. The Government’s Motion to Exclude the Opinion Testimony of Plaintiff’s Medical Witnesses

Plaintiff’s medical experts, Dr. Edward Taylor, an internist, and Dr. Alan Moshell, a dermatologist, reviewed the medical records regarding the administration of various medications to Mr. Hetherington, noted the condition of the patient at particular times, and concluded that metoprolol was the offending agent that caused the onset of toxic epidermal necrolysis.¹¹⁵

Specifically, Dr. Taylor’s report concludes that employees of the Cleveland Veterans Administration Medical Center breached the applicable standard of care by failing to appreciate that Mr. Hetherington’s deteriorating medical condition was likely caused by metoprolol.¹¹⁶ In support of this conclusion, Dr. Taylor points to the temporal proximity between the administration of metoprolol and the appearance of certain symptoms.¹¹⁷ It is significant to note that Dr. Taylor does not mention any of the numerous other drugs administered to Mr. Hetherington around the time of his death, or any of his serious underlying medical conditions. Instead, Dr. Taylor simply

Dunmar Corp., 43 F.3d 587, 599 (11th Cir. 1995) (“There is no burden upon the district court to distill every potential argument that could be made based upon the materials before it.”).

¹¹⁵ See doc. no. 54, Ex. A (Report of Dr. Edward Taylor); *id.*, Ex. B (Report of Dr. Alan Moshell).

¹¹⁶ See doc. no. 54., Ex. A (Report of Dr. Edward Taylor), at 2.

¹¹⁷ *Id.*

concludes that continued administration of metoprolol was “by far the most likely inciting agent for the development of fatal Toxic Epidermal Necrolysis, sepsis and death in this unfortunate patient.”¹¹⁸ He states that Mr. Hetherington’s death was the result of “poor medical management,” and that compliance with the standard of care required that metoprolol be discontinued.¹¹⁹

In like manner, Dr. Moshell’s report concludes that the continued administration of metoprolol was a breach of the standard of care and caused Mr. Hetherington’s death.¹²⁰ Dr. Moshell’s report does not describe Mr. Hetherington’s medical history, or the conditions from which he suffered. Like Dr. Taylor, Dr. Moshell’s report fails to mention any of the numerous other drugs administered to Mr. Hetherington near the time of his death. Based solely upon a review of the administration of metoprolol, Dr. Moshell determined that metoprolol repeatedly caused allergic skin reactions resulting in the development of toxic epidermal necrolysis, complications of which ultimately caused Mr. Hetherington’s death.¹²¹

His report concludes:

In summary, even though metoprolol is not a common cause of TEN [*toxic epidermal necrolysis*], in this case it is clear that it was the cause

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *See* doc. no. 54, Ex. B (Report of Dr. Alan Moshell).

¹²¹ *Id.*

of Mr. Hetherington's TEN. Given the prior episodes of drug reaction to metoprolol, it was below the standard of care for it to have been administered in September of 2003. Had it not been administered, then TEN would not have developed, and Mr. Hetherington would not have died of complications of TEN.¹²²

The government argues that the reports and testimony of both witnesses should be excluded on the ground that their opinions and theories of causation are not reliable.

1. *The legal standards*

The starting point for any discussion of the admissibility of opinion testimony offered by so-called "expert witnesses" is Federal Rule of Evidence 702. As amended in 2000, in response to the Supreme Court's decisions in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993),¹²³ *General Electric Co. v. Joiner*, 522

¹²² *Id.*

¹²³ The *Daubert* court made it clear that the requirement of reliability found in Rule 702 was the centerpiece of any determination of the admissibility of opinion testimony, 509 U.S. at 589, and the Court identified four factors to be used when determining the reliability of scientific evidence: (1) whether the theory can and has been tested; (2) whether it has been subjected to peer review; (3) the known or expected rate of error; and (4) whether the theory or methodology employed is generally accepted in the relevant scientific community. *Id.* at 593-94.

U.S. 136 (1997),¹²⁴ and *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999),¹²⁵

Rule 702 now provides that:

If scientific, technical, or other specialized knowledge *will assist the trier of fact* to understand the evidence or to determine a fact in issue, a witness *qualified as an expert* by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon *sufficient facts or data*, (2) the testimony is the product of *reliable principles and methods*, and (3) the witness has *applied* the principles and methods *reliably to the facts* of the case.

Fed. R. Evid. 702 (emphasis supplied). The requirements of this Rule can be grouped under three broad headings: *qualifications, reliability, and helpfulness*. See, e.g., *Frazier*, 387 F.3d at 1260; *Quiet Technology DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1340 (11th Cir. 2003) (discussing the “three part inquiry [used] to determine the admissibility of expert testimony under Fed. R. Evid. 702”).

Fidelity to the “gatekeeping role” imposed upon the trial court by the *Daubert*

¹²⁴ In *Joiner*, the Court established the standard for reviewing trial court rulings of admissibility, and held that such rulings would be made under an abuse of discretion standard. 522 U.S. at 141. The *Joiner* court also established the important test of analytical “fit” between the methodology employed by an expert witness and the conclusions drawn. *Id.* at 146. The court reasoned that just because a methodology is acceptable for some purposes, it may not be acceptable for others, and a court may not admit evidence when there is “simply too great an analytical gap between the data and the opinion proffered.” *Id.*

¹²⁵ In *Kumho Tire*, the Court made it clear that testimony based solely on the experience of an expert would not be admissible. 526 U.S. at 157. The expert’s conclusions must be based on sound scientific principles, and the discipline itself must be a reliable one. *Id.* at 156. The key consideration is whether the expert “employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Id.* The court emphasized that judges have considerable leeway in determining both how to test the reliability of evidence, and in deciding whether such evidence is reliable. *Id.* at 151-53.

decision¹²⁶ requires district court judges to

engage in a rigorous inquiry to determine whether: “(1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusion is sufficiently reliable as determined by the sort of inquiry mandated by *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.”

Rink v. Cheminova, Inc., 400 F.3d 1286, 1291-92 (11th Cir. 2005) (quoting *City of Tuscaloosa v. Harcross Chemicals, Inc.*, 158 F.3d 548, 562 (11th Cir. 1998) (footnote omitted)). *See also Frazier*, 387 F.3d at 1260 (“While there is inevitably some overlap among the basic requirements . . . they remain distinct concepts and the courts must take care not to conflate them.”).¹²⁷ The burden of satisfying the district court

¹²⁶ The *Daubert* decision held that the “general acceptance” test framed in *Frye v. United States*, 54 App. D.C. 46, 293 F. 1013 (D.C. Cir. 1923), “should not be applied in federal trials” because it had been superseded by the Federal Rules of Evidence enacted by Congress in 1975. *Daubert*, 509 U.S. at 588-89 & n.6. *See also General Electric Co. v. Joiner*, 522 U.S. 136, 142 (1997) (observing that *Daubert* held “that the ‘austere’ *Frye* standard of ‘general acceptance’ had not been carried over into the Federal Rules of Evidence”).

In place of the general acceptance standard, *Daubert* substituted *the trial court judge*, acting in the role of “gatekeeper” to the jury box, *see* 509 U.S. at 589 n.7, 597, and charged the judge with the “obligation” to “ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.” *Id.* at 589. *See also id.* at 594 (observing that Rule 702 “assign[s] to the trial judge the task of ensuring that an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand”), and 597 (same).

In procedural terms, this means that the trial judge is required to conduct “a preliminary assessment” pursuant to Federal Rule of Evidence 104(a) as to “whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.” *Id.* at 593-94.

¹²⁷ It is important to understand that this categorization really is nothing more than a rearrangement and consolidation of the explicit requirements of Rule 702. The first and third prongs of the Eleventh Circuit’s test (qualification and helpfulness, respectively) are taken from Rule 702’s preamble. *See* Fed. R. Evid. 702 (“If scientific, technical, or other specialized knowledge *will assist*

that these three elements are present in a given case falls upon the party proffering the expert witness. *See, e.g., Rink*, 400 F.3d at 1292 (“The party offering the expert has the burden of satisfying these three elements by a preponderance of the evidence.”) (citing *Allison v. McGhan Medical Corp.*, 184 F.3d 1300, 1306 (11th Cir. 1999)); *McDowell v. Brown*, 392 F.3d 1283, 1298 (11th Cir. 2004) (same); *Frazier*, 387 F.3d at 1260 (same).

a. Qualifications

The court finds, and the government does not dispute, that both of plaintiff’s medical experts are qualified by education and experience to offer opinion testimony. Therefore, the court need not discuss further Rule 702’s qualifications requirement.

b. Reliability

The reliability inquiry mandated by Federal Rule of Evidence 702 has three parts: the district court must ensure that “(1) the testimony is based upon *sufficient facts or data*, (2) the testimony is the product of *reliable principles and methods*, and

the trier of fact to understand the evidence or to determine a fact in issue, a witness *qualified as an expert* by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise”) (emphasis supplied). The major change accomplished by the Eleventh Circuit’s restatement is truncation of Rule 702’s three-part litmus test for methodological reliability. *See* Fed. R. Evid. 702(1)-(3). Clearly, that does not mean that district courts are to *ignore* the explicit language of Rule 702; on the contrary, the Eleventh Circuit’s formula simply recognizes that the three numbered prerequisites (and the additional thoughts imparted by the Supreme Court in *Daubert*) all relate to the same general concern: the reliability of the methodology utilized by the expert. Procedurally, then, the district court should consider satisfaction of those requirements separate and apart from qualification and helpfulness.

(3) the witness has *applied* the principles and methods *reliably to the facts* of the case.” Fed. R. Evid. 702 (emphasis supplied). Below, the court will address each of these requirements, but not in the order of their appearance in Rule 702. *Cf. Allstate Insurance Co. v. Hugh Cole Builder, Inc.*, 137 F. Supp. 2d 1283, 1287 (M.D. Ala. 2001) (“Because Defendants’ arguments concerning the sufficiency of the facts carry over into the application of the facts to the methods inquiry, the court will first examine whether the testimony is the product of reliable principles and methods[.]”).

i. Reliable principles and methods

As a result of the Supreme Court’s concern that jurors across the nation were at risk of being misled by purveyors of so-called “junk science,” *General Electric Co. v. Joiner*, 522 U.S. 136, 153 (1997) (Stevens, J., concurring in part and dissenting in part), the *Daubert* opinion imposed upon district court judges the responsibility for conducting “a preliminary assessment of whether the reasoning or methodology underlying the [proffered expert’s opinion] testimony is scientifically valid.” *Daubert*, 509 U.S. at 592-93. *See also* Fed. R. Evid. 104(a) (“Preliminary questions concerning the qualification of a witness . . . or the admissibility of evidence shall be determined by the court[.]”). The Court acknowledged that “[m]any factors will bear on this inquiry,” *Daubert*, 509 U.S. at 593, and emphasized the need to remain “flexible,” *id.* at 594, but nevertheless went on to provide five “general observations”

to assist district judges in assessing the reliability of the principles and methodology employed by a particular witness. *Id.* at 593. Specifically, the Court held that district judges may consider:¹²⁸ whether the theory or technique in question can be (and has been) tested; whether it has been subjected to peer review and publication; its known or potential error rate; the existence and maintenance of standards controlling its operation; and whether the theory enjoys widespread acceptance within the relevant scientific community. *Id.* at 593-94. The Court emphasized that “the focus . . . must be solely on *principles* and *methodology*, not on the *conclusions* that they generate.” *Id.* at 595 (emphasis supplied).

Both Dr. Taylor and Dr. Moshell claim to have used a methodology called “differential diagnosis” to reach their respective opinions in this case. In an affidavit filed almost eight months after the submission of his expert report, Dr. Taylor explained:

As one typically does in trying to determine the cause of TEN [*toxic epidermal necrolysis*], a physician goes through the process of looking at all of the reasonable explanations for a patient’s condition, and then determines through a process of elimination which cause is the most likely. This is commonly referred to as forming a “differential

¹²⁸ In *Kumho Tire*, the Court clarified that “a trial court *should* consider the specific factors identified in *Daubert* [only] where they are reasonable measures of the reliability of expert testimony [at issue in the case].” *Kumho Tire*, 526 U.S. at 152 (emphasis supplied). *See also id.* (“The trial court must have the same kind of latitude in deciding *how* to test an expert’s reliability . . . as it enjoys when it decides *whether or not* that expert’s relevant testimony is reliable.”) (emphasis in original).

diagnosis.” This is the process I used in examining Mr. Hetherington’s medical records seeking the likely cause of his TEN.¹²⁹

Dr. Moshell gave a strikingly similar explanation in his affidavit, which also was filed more than eight months after his expert report.¹³⁰

The Eleventh Circuit addressed the methodology allegedly employed by Doctors Taylor and Moshell in *McClain v. Metabolife International, Inc.*, 401 F.3d 1233 (11th Cir. 2005), and defined it as follows:

Differential diagnosis involves “the determination of which one of two or more diseases or conditions a patient is suffering from, by systematically comparing and contrasting their clinical findings.” *Dorland's Illustrated Medical Dictionary* 240, (Douglas M. Anderson et al. ed., 29th ed. 2000). This leads to the diagnosis of the patient’s condition, not necessarily the cause of that condition. *The more precise but rarely used term is differential etiology*, which is “a term used on occasion by expert witnesses or courts to describe the investigation and reasoning that leads to the determination of external causation, sometimes more specifically described by the witness or court as a process of identifying external causes by a process of elimination.” *See Mary Sue Henifin et al., Reference Guide on Medical Testimony*, in *Reference Manual on Scientific Evidence* 439, 481 (Federal Judicial Center, 2d ed. 2000). *The etiology of a disease is the cause or origin of the disease*

McClain, 401 F.3d at 1252 (emphasis added). Although several courts rightfully

¹²⁹ Doc. no. 56, Ex. 5 (Affidavit of Dr. Taylor), ¶ 4.

¹³⁰ *See* doc. no. 56, Ex. 4 (Affidavit of Dr. Moshell), ¶ 4 (“As explained in my deposition, when determining the cause or etiology of a condition, a physician goes through a process commonly referred to as a ‘differential diagnosis.’ In doing so, one looks at the various possible explanation for a patient’s condition and then determines which cause is the most likely one. This is the process I used in examining Mr. Hetherington’s medical records, seeking the likely cause of TEN.”).

have noted that significant differences exist between the formation of a “differential diagnosis” of a patient’s disease, and the process of seeking the “differential *etiology*” of the disease process, *see, e.g., Bowers v. Norfolk Southern Corp.*, 537 F. Supp. 2d 1343, 1360-62 (M.D. Ga. 2007),¹³¹ courts generally have used the terms interchangeably when evaluating expert opinions. Therefore, even though this court

¹³¹ As the Middle District of Georgia aptly observed in *Bowers v. Norfolk Southern Corp.*, 537 F. Supp. 2d 1343 (M.D. Ga. 2007), it is too easy to gloss over the distinctions between the definitions of the two terms, “differential diagnosis” and “differential etiology,” and to

conclude that they amount to a distinction without a difference. Indeed, courts in various circuits have admitted expert testimony supposedly based on the “differential diagnosis” method, when, in reality, the testimony is based on the “differential etiology” method. The distinction is more than semantic; it involves an important difference.

The difference arises from what is at stake in the two distinct methods and what that difference implies about the likely reliability of the expert’s opinions. When a doctor develops his differential diagnosis in treating a patient, two factors strongly insure that the doctor will follow a reliable methodology to diagnose the patient’s condition. First, if he misdiagnoses the patient’s condition, the patient may die. And second, if he misdiagnoses the patient’s condition and the patient dies, then the patient’s family will sue the doctor for medical malpractice.

By contrast, when an expert witness uses the differential etiology approach to testify in court to support a litigant’s case, he has very little at stake. He renders his opinion, and then gets paid, often quite handsomely. The plaintiff is at no risk of harm, and the expert will not get sued for malpractice.

The differential diagnosis method has an inherent reliability; the differential etiology method does not. This conclusion does not suggest that the differential etiology approach has no merit. It simply means that courts, when dealing with matters of reliability, should consider opinions based on the differential etiology method with more caution. It also means that courts should not conflate the two definitions.

Id. at 1360-61 (footnotes omitted) (emphasis supplied).

finds that the term “differential etiology” more aptly describes the methodology used by Doctors Taylor and Moshell, the court will, nevertheless, use the term “differential diagnosis” for the purpose of consistency with published opinions.

Six Circuits have held that a medical opinion on causation that is based upon a reliable differential diagnosis is sufficiently reliable to be admissible under Rule 702. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262-63 (4th Cir. 1999) (collecting cases from the First, Second, Third, Ninth, and D.C. Circuits). The Third Circuit found that the technique consists of a testable hypothesis, has been subject to peer review, contains standards for controlling its application in a particular case, has widespread acceptance in the medical community, and does not frequently lead to incorrect results. *See Heller v. Shaw Industries, Inc.*, 167 F.3d 146, 154-55 (3d Cir. 1999); *In re Paoli R.R. Yard PCB Litigation.*, 35 F.3d 717, 758 (3d Cir. 1994).

On the other hand, the Eleventh Circuit has found “in the context of summary judgment that differential diagnosis evidence by itself does not suffice for proof of causation.” *Rink*, 400 F.3d at 1295 (citing *Rider v. Sandoz Pharmaceuticals Corp.*, 295 F.3d at 1194, 1199 (11th Cir. 2002) (holding that even though some case reports “do contain details of the treatment and differential diagnosis,” such reports, nevertheless, “are not reliable enough, by themselves, to demonstrate the causal link the plaintiffs assert . . . because they report symptoms observed in a single patient in

an uncontrolled context’’)).¹³² The Eleventh Circuit has not entirely rejected the differential diagnosis methodology, however, explaining that

[u]nder certain circumstances, *circumstances that ensure reliability*, this approach may offer an important component of a valid methodology. This approach, however, will not usually overcome the fundamental failure of laying a scientific groundwork for the general toxicity of the drug and that it can cause the harm the plaintiff suffered.

McClain, 401 F.3d at 1252 (emphasis supplied). Although the *McClain* Court considered an expert’s use of the differential diagnosis methodology in the context of a toxic tort case involving a diet drug, the court’s reasoning has been applied to experts’ differential diagnoses of causation in other contexts. *See, e.g., Bowers*, 537 F. Supp. 2d at 1360-63 (applying the methodology to the opinion of an orthopaedist regarding the causation of the plaintiff’s back injury).

¹³² The entire context of the excerpt from the *Rider* opinion quoted in text is as follows:

Some case reports do contain details of the treatment and differential diagnosis. Even these more detailed case reports, however, are not reliable enough, by themselves, to demonstrate the causal link the plaintiffs assert that they do because they report symptoms observed in a single patient in an uncontrolled context. They may rule out other potential causes of the effect, but they do not rule out the possibility that the effect manifested in the reported patient’s case is simply idiosyncratic or the result of unknown confounding factors. As such, while they may support other proof of causation, case reports alone ordinarily cannot prove causation. *See, e.g., Haggerty v. Upjohn Co.*, 950 F. Supp. 1160, 1165 (S.D. Fla. 1996) (stating that “while case reports may provide anecdotal support, they are no substitute for a scientifically designed and conducted inquiry.” (citation omitted)), *aff’d without op.*, 158 F.3d 588 (11th Cir. 1998). The record demonstrates that the district court carefully considered the case reports and properly concluded that the case reports did not by themselves provide reliable proof of causation.

Rider v. Sandoz Pharmaceuticals Corp., 295 F.3d at 1199.

The Eleventh Circuit has made clear that an expert does not establish the reliability of his techniques or the validity of his conclusions simply by claiming that he performed a differential diagnosis on a patient. *See McClain*, 401 F.3d at 1253. Opinions based on a differential diagnosis are admissible only if the trial court determines that the expert reliably applied the differential diagnosis methodology. *See, e.g., Goebel v. Denver & Rio Grande Western Railroad Co.*, 346 F.3d 987, 999 (10th Cir. 2003); *see also Westberry*, 178 F.3d at 263 (“[A] *reliable* differential diagnosis provides a valid foundation for an expert opinion.”) (emphasis supplied). Thus, in evaluating the reliability of an opinion based on a differential diagnosis, courts consider the substance of the expert’s analysis, rather than just the label. *See Clausen v. M/V NEW CARISSA*, 339 F.3d 1049, 1057-1058 (9th Cir. 2003). The *McClain* Court explained:

No one doubts the utility of medical histories in general or the process by which doctors rule out some known causes of disease in order to finalize a diagnosis. But such general rules must . . . be applied fact-specifically in each case. *The underlying predicates of any cause-and-effect medical testimony are that medical science understands the physiological process by which a particular disease or syndrome develops and knows what factors cause the process to occur.* Based on such predicate knowledge, it may then be possible to fasten legal liability for a person’s disease or injury.

McClain, 401 F.3d at 1253 (quoting *Black v. Food Lion, Inc.*, 171 F.3d 308, 314 (5th Cir. 1999) (emphasis and omissions in original)).

ii. Application of principles and methodology to the facts

The Ninth Circuit’s opinion in *Clausen v. M/V NEW CARISSA*, *supra*, provides a comprehensive test for determining the reliability of a medical expert’s application of the differential diagnosis methodology to the facts of a particular case:

The first step in the diagnostic process is to compile a comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration. *See* [Jerome P. Kassirer & Richard I. Kopelman, *Learning Clinical Reasoning* 112 (1991)]. The issue at this point in the process is which of the competing causes are generally capable of causing the patient’s symptoms or mortality. Expert testimony that rules in a potential cause that is not so capable is unreliable. *See Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1413 (D. Or. 1996) (“[I]t is ... important to recognize that a fundamental assumption underlying [differential diagnosis] is that the final, suspected ‘cause’ . . . must actually be capable of causing the injury.”). Similarly, expert testimony that neglects to consider a hypothesis that might explain the clinical findings under consideration may also be unreliable. Including even rare entities in the list “ensures that such disorders are not overlooked.” *Clinical Reasoning*, *supra* n. 2, at 112; *see also Westberry*, 178 F.3d at 265 (“A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation.”).

After the expert rules in all of the potential hypotheses that might explain a patient’s symptoms, he or she must then engage in a process of elimination, eliminating hypotheses on the basis of a continuing examination of the evidence so as to reach a conclusion as to the most likely cause of the findings in that particular case. A district court is justified in excluding evidence if an expert “utterly fails . . . to offer an explanation for why the proffered alternative cause” was ruled out. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202 (4th Cir. 2001). The expert must provide reasons for rejecting alternative hypotheses “using scientific methods and procedures” and the elimination of those

hypotheses must be founded on more than “subjective beliefs or unsupported speculation.” *Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 502 (9th Cir. 1994).

Clausen, 339 F.3d at 1057-58.

(A) *Comprehensive list of hypotheses*

Both Dr. Taylor and Dr. Moshell fail the *Clausen* reliability test at step one. Neither doctor’s report includes a list, much less a comprehensive list, of hypotheses that might explain the development of toxic epidermal necrolysis in Mr. Hetherington. Neither witness attempts to explain the physiological process by which toxic epidermal necrolysis develops, or the factors that cause it to occur. Instead, both experts admit that there is no medical literature (other than the possibility of anecdotal case reports) to support their theory that metoprolol causes toxic epidermal necrolysis. In fact, both Dr. Taylor and Dr. Moshell admit that there have been no specific studies showing metoprolol to be a cause of toxic epidermal necrolysis.¹³³ In contrast, defendant’s expert, Dr. Boni Elewski, identified numerous, potential causes of the condition in her report:

TEN [*toxic epidermal necrolysis*] can occur as a result of several factors including drugs, underlying malignancy, bacterial or viral infection, and idiopathic. The most common drugs which are known to cause TEN include antibiotics, allopurinol, NSAIDS (nonsteroidal anti-inflammatory drugs), and anticonvulsants. There are a variety of other

¹³³ See doc. no. 56, Ex. 4 (Affidavit of Dr. Moshell); Ex. 5 (Affidavit of Dr. Taylor).

miscellaneous drugs that [sic] such as proton pump inhibitors which also might be culpable. Other etiologic cofactors include renal failure, immunosuppression and possibly underlying viral infections. Since TEN is idiosyncratic, its occurrence cannot be predicted.

The most common cause of TEN is drug-induced; antibiotics are often associated. Prior to the onset of TEN, Mr. Hetherington was treated with levofloxacin (an antibiotic) on 8/30 and 8/31 for an underlying infection, as well as with vancomycin (an antibiotic) on 8/28 to 8/31. Additionally, he was given a proton pump inhibitor, lansoprazole, on 8/24 through 8/29, which is another common cause of TEN. (Blume *et al.*) The onset of TEN after the offending drug varies from patient to patient, but is usually 1 to 2 weeks The TEN started approximately 14 days after the administration of the antibiotics levofloxacin and vancomycin, and the lansoprazole, so the timing of the eruption is within the expected boundry. Although TEN is often an idiosyncratic hypersensitivity reaction to medication, it is often attributed to infection, and Mr. Hetherington had an underlying infection requiring the above mentioned antibiotic therapy. Additionally, he had underlying heath issues including glomerulonephritis (p-anca positive with Sjogrens syndrome) requiring immunosuppressants, which could have contributed to the development of TEN.¹³⁴

(B) *Process of elimination*

Although both of plaintiff's medical witnesses claim to have engaged in a process of elimination before reaching their conclusions, neither of their respective reports consider any alternative hypothesis. Neither Dr. Taylor nor Dr. Moshell even mention the fact that Mr. Hetherington was administered numerous medications in addition to metoprolol. When asked if he had ruled out levofloxacin, vancomycin,

¹³⁴ Doc. no. 54 (Evidentiary Materials in Support of Plaintiff's Motion for Summary Judgment), Ex. E (Report of Dr. Elewski), at 1.

trimethoprin-sulfa, lansoprazole, autoimmune kidney disease, Sjogrens syndrome, or immunosuppressants as potential causes of Mr. Hetherington's development of toxic epidermal necrolysis, Dr. Taylor admitted that he had not ruled out those possible alternatives.¹³⁵ Dr. Moshell gave the same response during his deposition.¹³⁶

(C) *Reasons for rejecting alternative hypotheses*

Since neither doctor considered any alternative hypothesis for what may have led to the development of toxic epidermal necrolysis in Mr. Hetherington, it follows that they also failed to provide reasons for rejecting alternative hypotheses "using scientific methods and procedures." Because both Dr. Taylor and Dr. Moshell failed to apply the differential diagnosis methodology reliably in their respective evaluations of Mr. Hetherington's medical records, the court finds that their opinions do not meet the standard for reliability under Rule 702 and *Daubert* and are, therefore, due to be excluded.

c. *Assistance to the trier of fact*

The final requirement for admissibility of expert testimony under Rule 702 is that it assist the trier of fact. Testimony is only admissible if it concerns matters that are beyond the understanding of the average layperson. *See United States v. Rouco*,

¹³⁵ See doc. no. 51, Ex. 4 (Deposition of Dr. Taylor), at 17-19.

¹³⁶ See doc. no. 51, Ex. 5 (Deposition of Dr. Moshell), at 23-24.

765 F.2d 983, 995 (11th Cir. 1985). “Proffered expert testimony generally will not help the trier of fact when it offers nothing more than what lawyers for the parties can argue in closing arguments.” *Frazier*, 387 F.3d at 1262-63.

As discussed in more detail above, Doctors Taylor and Moshell have not provided any medical justification for their conclusions, aside from the temporal proximity of the administration of metoprolol to certain symptoms noted in Mr. Hetherington’s chart. Neither doctor provides any information regarding the connection of metoprolol to toxic epidermal necrolysis, or the reasons why metoprolol was found to be a more likely cause of the disorder than any of the other numerous medications administered to Mr. Hetherington. Furthermore, the doctors’ reports do not even mention the possible causes of toxic epidermal necrolysis, aside from disclosing that metoprolol is *not* a common cause. Both expert reports simply review notations made by the treating physicians at the Cleveland VAMC and make speculative opinions as to causation without disclosing any reasoning. The opinions of Dr. Taylor and Dr. Moshell, therefore, add nothing to plaintiff’s case apart from what plaintiff’s lawyers could argue to the jury.

Having failed to meet both the reliability and helpfulness prongs of the *Daubert* standard, the opinions of Doctors Taylor and Moshell are due to be excluded under Rule 702. Because plaintiff has presented no reliable evidence to demonstrate

causation, plaintiff has not established a prima facie case. Accordingly, defendant's motion for summary judgment will be granted.

C. Plaintiff's Motion to Exclude Dr. Goldstein and Motion for Summary Judgment

Pursuant to this court's finding that plaintiff has failed to present a prima facie case, and the resulting conclusion that summary judgment should be entered in favor of the government, plaintiff's motions will be denied as moot. An appropriate order consistent with this memorandum opinion will be entered contemporaneously herewith.

DONE this 18th day of November, 2009.



United States District Judge